

**Summary Minutes of the
Tobacco Products Scientific Advisory Committee
July 15-16, 2010**

Location: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd, Rockville, MD

All external requests for the meeting transcripts should be submitted to the CTP, Freedom of Information office.

These summary minutes for July 15-16, 2010 Meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on October 14, 2010.

I certify that I attended the July 15-16, 2010 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

**_____/s/_____
Cristi Stark, M.S.
Acting, Designated Federal Official, TPSAC**

**_____/s/_____
Jonathan Samet, M.D., M.S.
Committee Chair, TPSAC**

Meeting of the Tobacco Products Scientific Advisory Committee March 30-31, 2010

The Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on July 15-16, 2010 at the Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd, Rockville, MD. Prior to the meeting, members and invited consultants were provided copies of the background material from the FDA and the submissions from the public. The meeting was called to order by Jonathan Samet, M.D., M.S. (Committee Chair); the conflict of interest statement was read into the record by Cristi Stark, M.S. (Acting, Designated Federal Official). There were approximately 150 persons in attendance. There were 8 speakers for the Open Public Hearing session.

Issue: On July 15, 2010, the committee 1) received updates on upcoming committee business related to menthol, including Agency requests for information from industry on menthol cigarettes in order to prepare for the Tobacco Products Scientific Advisory Committee's required report to the Secretary of Health and Human Services regarding the impact of use of menthol in cigarettes on the public health, and 2) heard and discussed industry presentations on menthol in cigarettes as they relate to five topics: characterization of menthol, clinical effects of menthol, biomarkers of disease risk, marketing data, and population effects.

Specific areas of interest identified by the committee for industry presentations included:

Characterization of menthol

- 1) Trends in quantities of menthol present in the cigarette rod and smoke over time for various brands/subbrands of menthol and nonmenthol products as determined by the Cambridge Filter/ISO test method using standard parameters as well as the intense smoking conditions set forth in Canadian regulations.
- 2) Information regarding the manufacturing of menthol and nonmenthol cigarettes, including a) the source and type of menthol used, b) the presence or use of any menthol analogs, and c) the types of manufacturing processes through which menthol is introduced into the tobacco product, as well as the considerations in selecting a particular method.
- 3) The threshold (menthol content) at which a product is identified and marketed as a menthol cigarette and how that threshold is established.
- 4) The rationale for adding menthol to cigarettes not marketed as menthol cigarettes, and the criteria for determining the quantity of menthol to be added.
- 5) For international brands of menthol cigarettes, the quantities of menthol in both menthol and nonmenthol cigarettes sold internationally, and the factors considered in determining the quantity of menthol to be added.

Clinical effects of menthol

- 6) Studies of dose-response relationships for the physiologic effects of mentholated tobacco smoke.
- 7) Mechanistic studies of menthol effects including, a) chemosensory effects of menthol compounds in tobacco smoke, including effects at thermal and trigeminal receptors, b) the effect of menthol on the neurobiology of tobacco dependence, and c) the effect of menthol on clinical and behavioral measures.
- 8) Studies addressing the dosing relationship and the metabolic interactions between nicotine and menthol, including resulting perceptions of nicotine strength and the interaction between menthol delivery and nicotine/tar levels, for both low-menthol and high-menthol products.
- 9) Information on correlations between menthol content and consumer perceptions regarding a) taste, b) nicotine strength, and c) product harm.

Biomarkers

- 10) Analyses of laboratory and populations studies using biomarkers to assess the effect of menthol content on disease risk for cigarette smokers, based on cigarette consumption (e.g., cigarettes per day), including data related to menthol among population subgroups.

Marketing data

- 11) Data on consumer preferences for menthol cigarettes.
- 12) Consumer perception studies of advertising, packaging, and labeling of menthol cigarettes.
- 13) Marketing strategies for various brands/subbrands of menthol cigarettes, including strategies targeted to particular demographic groups.
- 14) Marketing strategies for various brands/subbrands of menthol cigarettes sold internationally.

Population effects

- 15) Among cigarette smokers, rates of switching from menthol to nonmenthol cigarettes and vice versa.
- 16) Comparative rates of initiation by youth and young adults with menthol and nonmenthol cigarettes.
- 17) Comparative rates of cessation for users of menthol and nonmenthol cigarettes.

On July 16, 2010, the committee continued discussion on topic 2.

Attendance:

July 15, 2010:

Tobacco Products Scientific Advisory Committee Members Present (Voting):

Jonathan Samet, M.D., M.S. (Committee Chair)
Neal Benowitz, M.D.
Mark Clanton, M.D., M.P.H.
Gregory Connolly, D.M.D., M.P.H.
Karen DeLeeuw, M.S.W. (State/Local Government)
Dorothy Hatsukami, Ph.D.
Patricia Nez-Henderson, M.P.H., M.D. (Public Representative)
Jack Henningfield, Ph.D.
Melanie Wakefield, Ph.D.

Industry Representative Members Present (Non-voting):

Luby Arnold Hamm (Tobacco Growers Representative)
Daniel Heck, Ph.D, D.A.B.T. (Tobacco Manufacturing Industry Representative)
John Lauterbach, Ph.D., D.A.B.T. (Small Business Tobacco Manufacturing Industry Representative)

Ex Officio Members Present (Non-Voting):

Ursula Bauer, Ph.D., M.P.H. (CDC)
Cathy Backinger, Ph.D., M.P.H. (NIH)
H. Westley Clark, M.D., J.D., M.P.H. (SAMHSA)
Susan Karol, M.D. (IHS)

FDA Participants (Non-Voting):

David Ashley, Ph.D.
Lawrence Deyton, M.S.P.H., M.D.
Corinne Husten, M.D., M.P.H.

Acting, Designated Federal Official:

Cristi Stark, M.S.

July 16, 2010:

Tobacco Products Scientific Advisory Committee Members Present (Voting):

Jonathan Samet, M.D., M.S. (Committee Chair)

Neal Benowitz, M.D.

Mark Clanton, M.D., M.P.H.

Gregory Connolly, D.M.D., M.P.H.

Karen DeLeeuw, M.S.W. (State/Local Government)

Dorothy Hatsukami, Ph.D.

Patricia Nez-Henderson, M.P.H., M.D. (Public Representative)

Jack Henningfield, Ph.D.

Melanie Wakefield, Ph.D.

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David Ashley, Ph.D.

Lawrence Deyton, M.S.P.H., M.D.

Corinne Husten, M.D., M.P.H.

Acting, Designated Federal Official:

Cristi Stark, M.S.

Open Public Hearing Speakers:

William Robinson, National African-American Tobacco Prevention Network

Jim Tozzi, Center for Regulatory Effectiveness (CRE)

David Johnson, Council of Independent Tobacco Manufacturers of America (CITMA)

Rod Lew, Asian-Pacific Partners for Empowerment, Advocacy and Leadership (APPEAL)

Phillip Gardiner, University of California

Jeff Stier, American Council on Science and Health

Pamela Clark, University of Maryland

Carol McGruder, African American Tobacco Control Leadership Council

The agenda was as follows:

July 15, 2010

Call to Order and Introductions

Jonathan Samet, M.D., M.S.

Committee Chair

Tobacco Products Scientific Advisory Committee

Conflict of Interest Statement

Cristi Stark, M.S.

Acting, Designated Federal Official

Tobacco Products Scientific Advisory Committee

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FDA Presentation

FDA Update on Upcoming Items
and Other Committee Requests for
Information on Menthol Cigarettes,

Corinne Husten, M.D., M.P.H.

Senior Medical Advisor, CTP, FDA

Questions to the Presenters

Industry Presentations

Characterization of Menthol

James E. Dillard III

Senior Vice President- Regulatory Affairs

Altria Client Services (on behalf of Philip Morris USA)

Jane Y. Lewis, Ph.D.

Senior Vice President- Health and Analytical Sciences

Altria Client Services (on behalf of Philip Morris USA)

Michael W. Ogden, Ph.D.

Senior Director- Regulatory Oversight

R.J. Reynolds Tobacco Company

William R. True, Ph.D.

Senior Vice President- Research & Development

Lorillard Tobacco Company

Questions to Presenters

Clinical Effects of Menthol

Jane Y. Lewis, Ph.D.

Senior Vice President- Health and Analytical Sciences

Altria Client Services (on behalf of Philip Morris USA)

Michael W. Ogden, Ph.D.

Senior Director- Regulatory Oversight

R.J. Reynolds Tobacco Company

William R. True, Ph.D.

Senior Vice President- Research & Development

Lorillard Tobacco Company

Questions to Presenters

Biomarkers of Disease Risk

Michael W. Ogden, Ph.D.

Senior Director- Regulatory Oversight

R.J. Reynolds Tobacco Company

Mohamadi A. Sarkar, Ph.D.

Senior Principal Scientist- Health Sciences
Altria Client Services (on behalf of Philip Morris USA)

William R. True, Ph.D.

Senior Vice President- Research & Development
Lorillard Tobacco Company

Questions to Presenters

Marketing Data

Pascal A. Fernandez

Vice President- Market Information & Consumer Research
Altria Client Services (on behalf of Philip Morris USA)

Monica J. Graves

Director- Marketing Operations
Regulatory Oversight
R.J. Reynolds Tobacco Company

Leonard H. Jones

Director- Direct Marketing & Marketing Research
Lorillard Tobacco Company

Questions to Presenters

Adjourn

The session adjourned @ approximately 5:20 p.m.

July 16, 2010

Call to Order and Introductions

Jonathan Samet, M.D., M.S.

Committee Chair
Tobacco Products Scientific Advisory Committee

Conflict of Interest Statement

Cristi Stark, M.S.

Acting, Designated Federal Official
Tobacco Products Scientific Advisory Committee

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FDA Overview and Welcome

Joshua Sharfstein, M.D.

Principal Deputy Commissioner
FDA

Industry Presentations

Population Effects

Geoffrey M. Curtin, Ph.D.

Director- Regulatory Science Development/Engagement
Regulatory Oversight
R.J. Reynolds Tobacco Company

Jennifer L. Hunter

Vice President- Corporate Affairs

Altria Client Services (on behalf of Philip Morris USA)

William R. True, Ph.D.

Senior Vice President- Research & Development
Lorillard Tobacco Company

Additional Questions to Presenters

Open Public Hearing

Question to the TPSAC Committee
and TPSAC Discussion

Closing Remarks

Adjourn

The session adjourned @ approximately 3:32 p.m.

Question to the committee:

- 1) (Discussion) In light of the July 15-16, 2010, TPSAC presentations, what future presentations would you like to request from industry on:
 - a) Characterization of Menthol in Cigarettes
 - i) Submission of menthol yields by brand and subbrand and over time by the Canadian Intense Method in addition to ISO – for top 5-10 brands
 - ii) *Submission of machine measured tar yields, menthol levels, and nicotine yield by brand and market share for menthol cigarettes – for top 5-10 brands. Time period: five years
 - b) Clinical Effects of Menthol Cigarettes
 - i) *What are the research (including chemosensory research), tests, measures used by each company to gather data from smoker panels for use in determining menthol levels in your cigarettes and the effects of menthol levels on product reference? Describe and provide your scales, questionnaires, and results. (Smoker panels includes expert smoke panels and consumer panels)
 - ii) *How are the data used in determining product characteristics including menthol levels?
 - iii) Who are on the consumer panels and what are their characteristics (e.g., age, race/ethnicity)?
 - c) Biomarkers of Disease Risk for Menthol Cigarette Smokers
 - i) Altria: Provide the full analytical dataset for TES to TPSAC and supporting documentation
 - ii) *Altria: Carry out biomarker analyses and time to first cigarette for smokers that smoke <10 cigarettes per day (cpd)
 - iii) RJRT: Provide the full analytical datasets and supporting documentation for your human exposure studies to TPSAC
 - d) Marketing Data on Menthol Cigarettes
 - i) What is the market share of non-menthol vs. menthol cigarettes over time for your products?

- ii) Provide a background document (not a presentation): Price of top menthol brand both before and after price promotion along with prices of non-menthol brands before and after price promotion
 - (1) Look at in different states
 - (2) Look at over time
 - (3) Look at segmented by tax changes (e.g., increases)
 - iii) Altria and RJRT: Present packaging and effects on consumer preferences and influence on consumer choice
 - iv) Lorillard: Submission of marketing by region – give all state segmentation
- e) Population Effects of Menthol Cigarettes
- i) Request that any data that is submitted to TPSAC be stratified by age, race, gender, cpd, and other variables as appropriate

* - considered by the TPSAC to be a high priority topic

Please see the transcript for detailed discussion.